DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

NDO Surgical, Inc.
Mr. Eric Bannon
Vice President of Regulatory,
Clinical and Quality Assurance
125 High Street, Suite 7
Mansfield, MA 02048

JUL 27 2015

Re: K023234
Trade/Device Name: Endoscopic Plication System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: ODE, GAW
Dated (Date on orig SE ltr): January 31, 2003
Received (Date on orig SE ltr): February 3, 2003

Dear Mr. Bannon,

This letter corrects our substantially equivalent letter of April 17, 2003.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K023234

Device Name: Endoscopic Plication System

Indications for Use: The NDO EPS System is indicated for the treatment of the symptoms of chronic gastroesophageal reflux disease (GERD) in patients who require and respond to pharmacological therapy.

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use____
(Per 21 C.F.R. 801.109)

(Optional Format 1-2-96)

Miriam C Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K023234

K023234 (P.1 of 2)

510 (k) SUMMARY

APR 17 2003

1. SUBMITTER:

NDO Surgical, Inc.
125 High St
Mansfield, MA 02048

Contact: Eric Bannon, Vice President of Clinical, Regulatory and Quality Assurance
Date Prepared: September 25, 2002

2. DEVICE:

Trade Name: NDO Surgical Endoscopic Plication System
Classification Name: Endoscope and Accessories
The Product Code: KOG

3. PREDICATE DEVICE:

The predicate device used to determine substantial equivalence for the NDO Surgical Endoscopic Plication System was the Bard EndoCinch Suturing System.

4. DEVICE DESCRIPTION:

The Endoscopic Plication System consists of an instrument, retractor, overtube and implant.

The instrument is passed transorally to create a plication in close proximity to the gastroesophageal junction.

The implant is designed to help pass and secure the suture.

The retractor is designed to secure and retract the tissue during the placement of the implant. It is placed down a working channel of the instrument prior to the procedure.

The overtube is designed to protect the esophagus during the procedure.

5. INTENDED USE:

The NDO EPS System is indicated for the treatment of the symptoms of chronic gastroesophageal reflux disease (GERD) in patients who require and respond to pharmacological therapy.

6. COMPARISON OF CHARACTERISTICS:

- The devices have the same intended and indication for use, have very similar technical characteristics and principles of operation.
- Bench and animal testing demonstrate that any minor technological differences do not raise any new questions of safety and effectiveness.
- The clinical comparison shows that the NDO Endoscopic Plication System to be at least as safe and effective as the Bard EndoCinch

7. PERFORMANCE DATA:

The following performance data was provided in support of the substantial equivalence determination:

- Mechanical evaluation
- In-Vivo safety study
- In-Vitro evaluation
- Clinical evaluation